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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,222	10/16/2001	Meir S. Sacks	MSS 49400	6524

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EXAMINER	
PRATS, FRANCISCO CHANDLER	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 12/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/981,222	SACKS ET AL.	
	Examiner	Art Unit	
	Francisco C Prats	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *4-7,10-12,14,16 and 23-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 8, 9, 13, 15, 17-22 and 34-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment filed October 3, 2003, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claims 34-36 have been added.

Claims 1-36 are pending.

Election/Restrictions

Applicant's election of the group I invention, claims 1-7, 13-18 and 22, directed to compositions comprising uric acid derivatives, in Paper No. 4, filed April 11, 2003, is acknowledged. Applicant's election of the species (a) xanthosine as the uric acid derivative, (b) vitamin C as the additional ingredient, (c) neurodegenerative disease as the disease to be treated, and (d) hypoxanthine as the uric acid precursor, is also acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 4-7, 10-12, 14, 16 and 23-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or

linking claim. As discussed immediately above, election was made **without** traverse in Paper No. 4, filed April 11, 2003.

Claims 1-3, 8, 9, 13, 15, 17-22 and 34-36 read on the elected invention of a composition comprising a uric acid derivative which is xanthosine and an additional ingredient which is vitamin C. Claims 1-3, 8, 9, 13, 15, 17-22 and 34-36 are therefore examined on the merits to the extent they read on the elected species.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 8, 9, 13, 15, 17-22 and 34-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, as amended the claims now recite that the composition comprises less than 1 gram of uric acid precursor. Thus, the claims encompass compositions comprising any amount of active ingredient less than 1 gram. While applicant does disclose compositions falling within that range, the current claim language encompasses active ingredient amounts, for example 10 mg, which are not disclosed in the specification as filed. That is, the specification as filed fails to support the entire range of the subject matter encompassed by the new language. This is particularly true in claims requiring both uric acid raising activity and a specific concentration because the claims now encompass concentrations which were clearly not contemplated by the originally filed disclosure to raise uric acid levels.

Also, the recitation "a maximum of 0.5 gram of the uric acid derivative" in new claims 34-36 lacks support in the disclosure as originally filed. There is nothing in the originally filed disclosure disclosing or suggesting such a maximum for the active ingredient amount. This is a new matter rejection.

Claims 1-3, 13, 15, 17, 18, 20, 22 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peeters et al (WO 94/00132).

As discussed in the previous office action, Peeters discloses the treatment of Alzheimer's disease with guanosine and precursors and/or derivatives thereof, including the elected species xanthosine, as well as guanine, inosine, xanthine, hypoxanthine, , 5' inosinic acid, and mono-, di- and triphosphates of guanosine. See claims 1-12, and amended claims 1-12, at pages 14-17 of the English language translation provided herewith. Thus, Peeters discloses pharmaceutical compositions comprising each of those compounds.

Peeters does not disclose that the pharmaceutical compositions should contain less than 1 gram of the elected species of compound xanthosine, as recited in the claims as now amended by applicant. However, as discussed in the previous office action, Peeters discloses that the elected species xanthosine should be administered at dosages of from 20 mg/kg/day to 150 mg/kg/day. See translation at page 11, lines 3 and 4. Assuming a 50 kg person, this dosage would result in an administration of compositions comprising 1 to 7.5 grams per day. The artisan of ordinary skill clearly would have recognized that a suitable method of administering 1 gram of

xanthosine, or more, per day would have been by administering in 500 mg oral dosage forms. Official notice is taken of the fact that the determination of suitable dosage regimens for the therapeutic methods in Peeters, including the use of 500 mg dosage forms, was clearly well within the purview of the artisan of ordinary skill at the time of applicant's invention. Therefore, the claims must be considered obvious under § 103(a), absent some demonstration of an unexpected result coming from the claimed use of dosage forms containing less than 1 gram, or no more than 500 mg of xanthosine.

Claims 1-3, 8, 9, 13, 15, 17-22 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peeters et al (WO 94/00132) in view of Howard et al (GB 2 280 110).

As discussed above, Peeters renders obvious the treatment of Alzheimer's disease using compositions comprising the claimed amounts of guanosine and precursors and/or derivatives thereof, including the elected species xanthosine, as well as guanine, inosine, xanthine, hypoxanthine, 5' inosinic acid, and mono-, di- and triphosphates of guanosine. Peeters differs from the claims in that Peeters does not disclose the inclusion of the

elected additional ingredient vitamin C in described compositions.

However, Howard discloses that vitamin C should be included in a regimen of treating Alzheimer's. See claim 5 on page 27, also claim 14 on page 29. Thus, the artisan of ordinary skill, reasonably expecting the vitamin C of Howard to be beneficial in Peeters' method of treating Alzheimer's, clearly would have been motivated to have included Howard's vitamin C in the therapeutic regimen disclosed by Peeters. A holding of obviousness is clearly required.

Note that it is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Response to Arguments

All of applicant's argument regarding the pending grounds of rejection has been fully considered but is not persuasive of error. While applicant urges that the claimed amounts of xanthosine recited in the claims as amended distinguish over Peeters, this argument ignores the fact that the artisan of ordinary skill would have readily recognized that the daily dosages described in Peeters would have been suitably administered using the claimed compositions. For example, at the time of applicant's invention, a maximum daily dosage of aspirin could have been considered to be about 8 grams. Despite this, it was well known at the time to dispense aspirin commercially in tablets of 500 mg. Thus, in the case of the xanthosine described by Peeters to be useful at a dosage of 1 to 7.5 grams per day, the artisan of ordinary skill clearly would have had a reasonable expectation that dosage forms of 500 mg would have been suitable. A holding of obviousness is therefore clearly required.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is

reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Francisco C Prats
Primary Examiner
Art Unit 1651

FCP